REMARKS

Claims 1-8 are pending in this patent application. By this amendment, claim 2 has been canceled, claims 3 and 7 have been amended, and claims 9-20 have been added. Reconsideration of this patent application, as amended, is respectfully requested.

35 U.S.C. § 112 Rejection

Claims 2 and 3 were rejected under 35 U.S.C. § 112, first paragraph. In order to advance the prosecution of this patent application, claim 2 has been canceled. Further claim 3 has been amended so as to further define the location of "the sensor" set forth in claim 1. Amended claim 3 is believed to comply with 35 U.S.C. § 112.

35 U.S.C. § 103 Rejection

Claims 1-8 were rejected under 35 U.S.C. § 103 as being unpatentable over Brown et al. (U.S. Patent No. 5,842,785) in view of Cohen et al. (U.S. Patent No. 5,980,527), and further in view of Draenert et al. (U.S. Patent No. 4,671,263), and still further in view of EP 0 444 842 A2 (hereinafter EP '842). Claim 2 has been canceled, and claim 3 has been amended to more clearly define the invention. Reconsideration of claims 1 and 3-8 is respectfully requested.

Claim 1 is Not Unpatentable Over a Combination of Brown, Cohen, Draenert, and EP '842

Claim 1

Claim 1 recites the following limitations:

> e. a sealing component which fits over the bone cavity to seal the cavity around the chamber outlet and to minimise leakage of bone cement that has been injected into the cavity,
> f. a sensor for measuring the pressure to which the bone cement is subjected during displacement from the chamber,
> *in which the sensor is located in the sealing component*.
> (Emphasis added.)

Brown and Cohen do not disclose a sensor for measuring pressure. While Draenert appears to disclose the use of a sensor for measuring pressure, Draenert does not disclose locating the sensor in the sealing component. (See Draenert at column 5, lines 41-50.) In addition, EP '842 discloses a pressure applying apparatus 10 (see, e.g., Fig. 1). The pressure applying apparatus 10 includes an inflatable sealing member 24. (See Abstract, line 3.) No sensor is located in the sealing member 24. Rather, EP '842 provides a pressure gauge 50 that can sense or measure pressure via passageways 48 and 36 which are in fluid communication with the inflatable sealing member 24. (See, e.g., EP '842 at column 5, lines 11-28; and Fig. 2.)

Thus, even if it were obvious to combine Brown, Cohen, Draenert, and EP '842 as proposed in the Office Action (see Office Action at page 4, lines 12-16), the resulting combination would not arrive at a system in which the sensor is located in the sealing component. Accordingly, the proposed combination of

Brown, Cohen, Draenert, and EP '842 would not arrive at the invention of claim 1. Thus, the proposed combination does not establish a prima facie case of obviousness under 35 U.S.C. § 103 with regard to the invention defined in claim 1. As a result, claim 1 is allowable over Brown, Cohen, Draenert, and EP '842.

Further, in the Office Action (at page 4, last six lines), it appears that the Examiner alternatively takes the position that it would have been obvious to further modify the combined Brown, Cohen, Draenert, and EP '842 apparatus with "known options within his or her technical grasp." However, even if it were obvious to combine Brown, Cohen, Draenert, and EP '842 with "known options within his or her technical grasp", the resulting combination would still not arrive at the claimed device. Significantly, locating a sensor in a sealing component which fits over a bone cavity to seal the cavity is not a *known option*. So modifying the combined Brown, Cohen, Draenert, and EP '842 would not result in a system that includes this claimed feature. As a result, this alternative proposed combination does not establish a prima facie case of obviousness under 35 U.S.C. § 103 with regard to the invention defined in claim 1.

Further Considerations

The present invention has many benefits over the prior art. For example, by locating the sensor in the sealing component, more accurate measurement of pressure can be achieved of the freshly mixed and injected bone cement within the bone cavity. As a comparison, the Draenert device could falsely indicate that a very high pressure is being applied to the cement in the bone cavity when in

fact only a relatively low pressure is present. Indeed, in Draenert, there will be a drop in pressure between the mixing chamber and the bone cavity, and the pressure drop could vary due to a wide range of factors, including the shape of the bone cavity, the shape of the injection nozzle and other components. And more significantly, the pressure drop will vary widely based on the extent of cure (viscosity) of the cement (e.g. in the nozzle). As the cement starts to cure, the pressure will correspondingly be not transmitted to the cement in the bone cavity. This appears to be similar to what is seen in the Brown document.

The present invention therefore decouples pressure in the cement within the bone cavity from dependence on variables such as the extent of cure of the cement in the injection nozzle. This is important. With the Draenert and Brown devices, it could easily be that, in order to achieve a desired level of pressure in the bone cavity, a higher pressure has to be generated in the delivery device because of pressure drop in the dispensing nozzle. This pressure drop would not be visible and would mean that there is a loss of control. Applicants' solution to this problem represents a significant advantage in comparison to what is taught by Draenert and Brown.

If a skilled artisan reading Draenert, Brown and the other cited references were for some reason inclined to combine the teachings of the cited references, the present invention would not be the result. As discussed above, the teachings of the Draenert and Brown documents appear to be largely equivalent. Those and the EP '842 document rely on a pressure gauge which is located in a device which supplies pressurized fluid to the bone cavity. In the case of Brown and

Draenert, the fluid is the bone cement and in the case of EP '842, the fluid is air. In other words, each of these prior art devices measures the pressure in the fluid that is supplied to the bone cavity upstream of the cavity. One skilled in the art looking to modify the Brown and Draenert devices, who then reads the EP '842 document, will be provided with another teaching to provide pressure control by supply of a pressurized fluid. (In the case of EP '842, it would be air rather than cement.) This actually teaches away from the present invention. In the present invention, the advantages arise from the fact that it is the supply of pressurized cement that is relied on to generate pressure in the bone cavity. This means that the device can be kept simple. It also means that the controlled pressure in the cavity is generated while the cement is at the stage in its cure when it is suitable for supply to the cavity (that is to say, it is still in the early stages of cure and therefore less viscous). The present invention can then use a pressure gauge which measures the pressure in the bone cavity directly by taking the pressure measurement from the seal for the cavity, rather than relying on measurement upstream of the cavity in a pressurized fluid which is being supplied to the cavity. Accordingly, in addition to the simplicity of the pressure measuring components, the invention has the advantage of enabling pressure measurements with greater accuracy.

In conclusion, none of the cited references provides the skilled artisan with a teaching of how to achieve accurate measurements of the cement pressure within a bone cavity, combined with a simple device which also enables the application of pressure in a reliable and controlled way at a stage in the

procedure when the cement has a relatively low viscosity and is therefore better able to respond to the applied pressure to achieve secure bone fixation.

Claims 3, 4, 6, and 8

Each of claims 3, 4, 6, and 8 depends directly or indirectly from claim 1. As a result, each of claims 3, 4, 6, and 8 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 1.

Claim 5

The discussion concerning the patentability of claim 1 is relevant to the patentability of claim 5. Thus, for at least the reasons hereinbefore discussed with regard to claim 1, claim 5 is allowable over the cited art.

Amended Claim 7

The discussion concerning the patentability of claim 1 is relevant to the patentability of amended claim 7. Thus, for at least the reasons hereinbefore discussed with regard to claim 1, amended claim 7 is allowable over the cited art.

New Claims 9-20

Each of claims 9-15 depends directly or indirectly from claim 1. As a result, each of claims 9-15 is allowable for, at least, the reasons hereinbefore discussed with regard to claim 1. In addition, each of claims 16-20 depends directly or indirectly from amended claim 7. As a result, each of claims 16-20 is

allowable for, at least, the reasons hereinbefore discussed with regard to amended claim 7. Also, each of claims 9-20 recite additional novel and non-obvious features such as positioning the sensor at a distal surface of the sealing component. Thus, each of claims 9-20 is additionally allowable over the cited art.

Conclusion

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited. It is respectfully submitted that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response, and any deficiency in fees be charged, or any overpayment in fees be credited, to our Deposit Account No. 13-0014.

Respectfully submitted,

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